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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Jonathan Stinson**
Application No.:	**10/037036**
Filed:	**October 25, 2001**
For:	**Balloon Expandable Polymer Stent With Reduced Elastic Recoil**
Group Art Unit:	**3731**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-9919-US01

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **2** page transmittal letter, we are submitting the attached:
20 Page Brief On Appeal (in triplicate); Check in the amount of $500.00 and a Postcard.

2. With respect to fees:
   - ☐ No additional fee is required.
   - ■ Attached is check(s) in the amount of $500.00
   - ■ Charge any fee deficiency to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 14, 2005

By: _____
Walter J. Steinkraus
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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Certificate Under 37 CFR 1.8: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as FIRST CLASS MAIL, addressed to Mail Stop Appeal Brief-Patents, Commissioner for Patent, P.O. Box 1450, Alexandria, VA 22313-1450, on February 14, 2005.

Heidi J. Steuter

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BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 1-23 were finally rejected in an Office Action mailed October 5, 2004. A Notice of Appeal was filed in this case on December 17, 2004. This brief is submitted in accordance with 37 C.F.R. § 41.37:

> *(a)(1) Appellant must file a brief under this section within two months from the date of filing the notice of appeal under §41.31.*
>
> *(2) The brief must be accompanied by the fee set forth in §41.20(b)(2).*
>
> *(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.*

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter.

> *(c)(1) The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:*

(i) Real Party in Interest

> *(i) Real party in interest. A statement identifying by name the real party in interest.*

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN

55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

(ii) Related appeals and interferences. A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.

No related appeals or interferences are pending.

(iii) Status of claims

(iii) Status of claims. A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.

Claims 1-23 are pending and have been rejected. No claims have been allowed, withdrawn, objected to or cancelled. The claims that are being appealed are 1-23.

(iv) Status of amendments

(iv) Status of amendments. A statement of the status of any amendment filed subsequent to final rejection.

No amendment was filed subsequent to final rejection.

(v) Summary of claimed subject matter

(v) Summary of claimed subject matter. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

Claims 1-23 pertain to processes for forming medical devices from polymer materials, especially polymer stents, and to medical devices produced thereby. The required

references to the specification and drawings are provided in brackets in the claim summaries below.

The invention provides a novel technique by which the molecular orientation of a formed polymer stent or a tubular stent preform can be improved to increase hoop-wise orientation. The process is particularly suited to balloon expandable polymer stents. Such stents typically have suffered from high elastic recoil after release of balloon inflation pressure [p. 4, ln.14-23].

According to independent claim 1, a generally tubular stent of the polymer material is formed [p.5, lines 7-9; Fig.1; p. 8, ln.1-10]. Examples of how this step may be done include molding, welding a pattern-cut sheet, and cutting or etching a pattern into a cylindrical tube.

The formed stent is then radially expanded to produce an expanded diameter stent [p.5, ln. 10-20; Fig. 2]. Examples of how this may be done include using an expanding mandrel or collet, sliding over a tapered mandrel, and expansion with a balloon. The purpose of this step is to cause the molecular structure of the polymer to orient itself around the hoop, stretching causing molecular alignment in the direction of the elongation and increasing strength in the direction of orientation [p.8, ln.22-29]

Then, the expanded diameter stent is annealed to shrink its diameter to a reduced diameter [p.5, ln. 21-25; Fig.3]. The purpose of the annealing step is to reduce or eliminate residual elastic stresses and to shrink the stent to size for deployment [p.9, ln.15-21].

According to dependent claim 2, the steps of radially expanding the stent and of annealing the expanded diameter stent are repeated at least once in sequence [p.5, ln.25-27]. The annealing step causes some loss of orientation. Repetition of the radial expansion and annealing steps improves final molecular orientation by an incremental additive mechanism. [p. 9, ln.19-25].

According to dependent claim 3 the stent is formed by molding the polymer material [p. 8, ln.1].

According to dependent claim 9 the step of radially expanding the stent is performed at room temperature [p.5, ln. 12-14].

In dependent claim12, a thermoplastic polymer stent having a molecular orientation as obtained by a process as in claim 1 is claimed. [p.5, ln.28 - p.6, ln.2; Figs 3-5; p. 9, ln. 1-7; Fig. 7]. In independent claim 13 a thermoplastic polymer stent having a hoopwise molecular orientation is claimed.

In independent claims 15, 17 and 21 the radial expansion and annealing steps are performed on a tubular article [p. 11, ln.23 - p. 12, ln. 9]. According to claim 15, the radial expansion and annealing steps are repeated at least once in sequence [p. 12, ln.5]. According to claim 17 the polymer material is biodegradable [p.12, ln.5-6]. According to claim 21, after the annealing step (c) a stent form is fashioned from the tube [p. 12, ln. 69].

(vi) Grounds of Rejection to be Reviewed on Appeal

(vi) Grounds of rejection to be reviewed on appeal. A concise statement of each ground of rejection presented for review.

Review on appeal is requested of the Examiner's contention that Stinson (US 6,245,103), a commonly owned prior patent of the present inventor, anticipates claims 1-23. In particular for specified claim subgroups, applicant disputes the Examiner's contentions a) that Stinson shows an annealing step performed after a radial expansion step b) that repetition of the radial expansion and annealing steps in sequence is shown in the Stinson patent; c) that the Stinson patent shows a polymer stent formed by molding or etching; e) that the Stinson patent shows a radial expansion step performed at room temperature; e) that the Stinson patent shows stents having "hoopwise" molecular orientation; and f) that Stinson patent shows a process in which a stent pattern is formed from a tube that has first been subjected to sequential radially expansion and annealing steps.

Review on appeal is also requested of the Examiner's contention that claims 1, 13, 15, 17 and 21 are obvious from Andrews et al (US 6,156,254) in view of Lennard et al (US

4,911,165). In particular applicant disputes a) that the Andrews patent shows a step of forming a stent, that Andrews has a col. 12, lines 25-28, that polypropylene filaments of Lennard et al have any relevance to the Andrews stent, and that motivation to combine the Andrews stent with Lennard sutures has been articulated. Additionally, for specified claim subgroups the applicant disputes: b) that the combination anywhere describes or suggests a process for forming a polymer stent; c) that a polymer stent, much less a polymer stent having hoopwise orientation, is taught or suggested by the combination; d) that repetition of the radial expansion and annealing steps in sequence is shown in the combination; e) that a polymer stent of biodegradable material is taught or suggested by the combination; and f) that the combination teaches or suggests a process in which a stent pattern is formed from a tube that has first been subjected to sequential radially expansion and annealing steps.

(vii) Argument

(vii) Argument. The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to §41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.

1. The Examiner Erred in rejecting claims 1-23 as anticipated by Stinson et al US 6,245,103

a. Claims 1-12 and 15-23 - Annealing of a Radially Expanded Stent or Tube

Anticipation under 35 U.S.C. Section 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.* , 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *In re Robertson*, 49 USPQ2d 1949 (Fed. Cir. 1999). The Stinson patent does not anticipate any of claims 1-23.

The Examiner contends:

> Stinson discloses in figs 1, 4, 14 and table 6, a process for forming a stent having the limitations of claims 1-2, 12,15,17-18 and 21-22, including: the process comprises the step of forming a tubular stent (10) of the polymer material (see col. 16, lines 21-27); the stent radially expanding to produce an expanded diameter stent, ***annealing the expanded diameter stent that shrinks from its expanded diameter to a reduced diameter (see col. 12, lines 25-28 and col. 16, lines 27-67),*** and at least one time repeating of steps b) and c) in sequence. ***(emphasis added)***

The Examiner is clearly wrong.

The stents of the Stinson patent are polymer stents formed from polymers. The process and the products formed, however, are very different from the inventions of claims 1-23 of the present application. The Stinson stents are formed by braiding polymer fibers onto a mandrel and then annealing the braided stent onto a second mandrel of smaller diameter. After the annealing step the stent is stretched longitudinally to a further reduced diameter at which it is

delivered. Upon delivery, the stent will *self-expand* to a deployed diameter less than the annealed diameter. The difference between the braid mandrel diameter and the anneal mandrel diameter can be varied to give a desired deployed diameter with in a predetermined range. Determination of the what the deployed diameter will be for a particular stent configuration, and what the radial force at a fraction thereof will be, is described and exemplified at col. 15, ln. 40 - col. 17, ln. 9. Separate stents are used with the different anneal mandrels to provide the reference data [*see in particular* col. 17, ln. 4-9]. The data can be used to formulate linear equations that enable prediction of annealed stent diameter that will yield a target radial force value, or the deployed stent diameter from the annealed stent diameter, for a given braid design and delivery system size.

Column 12, lines 25-28 of the Stinson patent, cited by the Examiner, is irrelevant to the subject matter of the present invention. It pertains to testing done on polymer *filament* properties to determine whether annealing would significantly change strength or modulus properties of the filaments (col. 11, ln. 20-30). This is a test. There is no indication that, in a stent forming process, the filaments are to be annealed before they are braided into the stent. Moreover, even if the filaments were annealed before they were braided into stents, such a process would be irrelevant to the process of the invention which only recites annealing of the stent. The filaments used to braid the Stinson patent stents are not themselves stents or tubular medical articles. Consequently, the Examiner has clearly erred in citing col. 12, lines 25-28 of the Stinson patent to justify his anticipation rejection.

The citation of col. 16, lines 27-67 is equally inapt. This is a portion of the passage that we have already shown describes how to formulate linear equations that enable prediction of annealed stent diameter that will yield a target radial force value, or the deployed stent diameter from the annealed stent diameter, for a given braid design and delivery system size. It does not teach anything about annealing an expanded diameter stent. Annealing is performed on the stent as formed.

As recited in claim 1, the "expanded diameter stent" is the product of a radial expansion step (b) performed on the already formed stent. It is this "expanded diameter stent" that is subjected to the annealing step (c), not the stent as formed. This is made absolutely clear in step (c) both from the word "then" in the lead-in to step (c) and in step (c)'s the reference to

"the expanded diameter stent," which necessitates that we treat the product of step (b) as the starting point for step (c). This is elementary method claim language. There is nothing tricky about the proper construction of the claim language.

The stent of the Stinson patent is annealed from the stent diameter as formed, not from a "radially expanded diameter." The Stinson patent stent is not subjected to a radial expansion step until it is deployed, or in the case of the tests discussed in col. 16 when it is tested subjected to testing to determine deployed diameter and radial force. No annealing step takes place after such radial expansion. The stent of the Stinson patent is annealed before radial expansion occurs. The Stinson patent sequence described at col. 5, lines 31-39:

> ... make the stent at a particular diameter (A), anneal the stent at a smaller diameter (B), and deploy the stent from a delivery system of diameter (C) whereby the stent will be "programmed" to self-expand to a desired implant diameter (D). The relationship between the diameters is A>B>D>C.

In this sequence diameter D is the only diameter that is achieved by a radial expansion step and hence the only "radially expanded" diameter. Diameter D is achieved after the annealing step has been performed. Therefore the Stinson patent does not anticipate the process of claim 1 and its dependents.

A parallel construction applies to the article forming steps of independent claims 15, 17 and 21. Therefore the Stinson patent does not anticipate these claims or their dependents.

At least for the reasons just given the anticipation rejection of claims 1-23 should be reversed.

b. Claims 2, 15-16, 18, and 22 - Repetition of the Radial Expansion and Annealing Steps in Sequence

Claims 2, 15-16, 18, and 22 require repetition of steps (b) and (c) at least one time in sequence. The Examiner contends that the same passages of the Stinson patent show this. The applicant has no idea what the Examiner is thinking. The Stinson patent does not show repetition of radial expansion and subsequent annealing steps on a formed stent.

c. Claims 3 and 23 - Polymer Stent Formed By Molding or Etching

"Regarding claims 3 and 23," the Examiner asserts in the Final Action, "Stinson discloses the stent is formed by molding or etching the polymer material (see col. 1, lines 43-66). Once again, the Examiner is clearly wrong.

Column 1, lines 43-66, of the Stinson patent is in the Background section of the patent and pertains to metal stents, not polymer material stents. No mention of molding or etching, much less of molding or etching a polymer stent, is found in this location. The polymer stents of the Stinson patent are made by braiding polymer filaments, not by molding.

d. Claim 9 - Radial Expansion Step Performed At Room Temperature

"Regarding claims 8-9," the Examiner asserts in the Final Action, "Stinson discloses the process has a temperature that is below the glass transition temperature of the polymer material; and wherein the step b) performs at room temperature (see col. 19, lines 22-50)."

The Stinson patent does not show a radial expansion step at the cited location. A stent is formed on a braid mandrel, annealed at a temperature between glass transition temperature and melting temperature of the polymer material, and then cooled to room temperature. Cooling to room temperature after annealing is not radially expanding the stent at room temperature before annealing.

e. Claims 12-14 "Hoopwise" Molecular Orientation

"Regarding claims 13-14," the Examiner asserts in the Final Action, "Stinson discloses the stent has a hoop or circular orientation (see figs 1); and wherein the polymer is biodegradeable (see col. 2, lines 7-60)."

Claim 13 recites a thermoplastic polymer stent having a "hoopwise molecular orientation." Claim 14 depends from claim 13.

The hoopwise molecular orientation is substantially circular, as shown in Fig. 7 and discussed at page 8, line 22 - page 9, line 5. The Stinson patent stents are formed from longitudinally oriented fibers wound in a helical braid of crossing fibers. The orientation is not substantially circular. Even assuming that the molecular orientation in the Stinson patent stent follows the longitudinal axis of the fibers, there is a substantial longitudinal component to each

fiber winding. For this reason the Stinson patent does not disclose a stent which anticipates claim 13 or claim 14 which depends therefrom.

Because the process of claim 1 changes the molecular orientation of a stent toward a hoopwise orientation, the product of that process, recited in claim 12 is also seen to be patentably distinguished from the Stinson patent stents.

f. Claims 21-23 - Stent Pattern Formed From a Tube That Has First Been Subjected To Sequential Radially Expansion and Annealing Steps

Independent claim 21 recites a process for forming a polymer stent which also includes sequence recitations. In claim 21 a polymer tube is formed, radially expanded, ***the radially expanded tube*** is annealed, ***and subsequently*** the stent is formed ***from the annealed tube***. That is, the stent pattern is provided ***after*** the tube has been both b) radially expanded and c) annealed at least one time. This may be accomplished, for instance, by machining or etching the tube after the steps b) and c) have been performed.

In the braided stent of the Stinson patent, tube formation and stent pattern formation are the same step, *i.e.* braiding the tube over a mandrel. There is no teaching or suggestion of the process sequence as recited in claim 21.

2. The Examiner Erred in rejecting Claims 1, 13, 15, 17 and 21 as Obvious over Andrews et al US 6156254 in view of Lennard et al US 4,911,165

Claims 1, 13, 15, 17 and 21 have been rejected under 35 USC 103 (a) over Andrews et al. (US 6,156,254) in view of Lennard et al (US 4,911,165). The rejection must be reversed.

a. Claims 1, 13, 15, 17 and 21 - Misconstruction of References, Confusing Assertions, Absence of Motivation

To support an obviousness rejection, the cited prior art must specifically suggest the combination as claimed, and it must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the solution. It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the

various documents to supply elements to fill the gaps. The cited documents themselves must provide some teaching whereby the applicant's combination would have been obvious, again at the time the invention was made. US patent law is replete with cases that illustrate this principle. *See e.g. In re Fine,* 37 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); *In re Kotzab,* 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); and *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir.1999). The Examiner has not made the requisite showing.

The Examiner begins the explanation of the rejection on pages 3-4 of the Final Office Action as follows:

> Andrews et al show in fig. 10, a process having all the limitations of claims 1, 13, 15, 17 and 21, including: the step of forming a tubular stent (10); the stent radially expands to produce an expanded diameter stent. However, Andrews et al do not disclose the step of annealing the expanded diameter stent that shrinks its diameter to a reduced diameter (see col. 12, lines 25-28).

This is not correct.

Andrews et al shows a stent in Fig 10 "which is a coil of stainless steel" (col. 9 lines 19-24). Stainless steel is metal. Claims 1, 13, 15, 17 and 21 all pertain to processes or articles made of polymer, not metal. The Andrews et al stent is irrelevant to the present application. A skilled person will not look to this document to find a polymer stent or a process for forming a polymer stent.

Even if the stainless steel stent of Andrews et al were relevant to the application, it does not show a step of forming a tubular stent as asserted in the Office Action. Andrews et al pertains to a balloon formation process, not to a stent formation process. It teaches ***nothing*** about forming the stainless steel coil stent of Figure 10.

The Final Office Action fails to indicate how the sequence recited in claims 1, 15, 17 or 21 are believed to be taught or suggested by Andrews et al. No such teaching exists.

The Final Office Action refers to "col. 12, lines 25-28." There is no such location. The Andrews et al patent ends at the bottom of column 10.

Continuing with the explanation of the rejection, the Examiner states on page 4 of the Final Office Action:

> Lennard et al teach using polypropylene filaments then annealed in an oven and allowed to shrink from about certain percent of the original length (see col. 4, lines 55-65).
>
> It would have been obvious to one having ordinary skill in the art at the same time the invention was made to modify Andrews et al by adding polypropylene filaments then annealed in an oven and allowed to shrink as taught by Lennard et al et al in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature. Furthermore, it will increase the final molecular orientation of the stent.

This is not understood.

Lennard et al pertains to surgical filament sutures. It doesn't pertain to stents at all, much less to polymer stents. How is the examiner proposing to accomplish "adding" the filaments? Are the polypropylene fibers being used in some way as sutures? If not, why are suture filaments being used? Are they being used to form part of the Andrews et al stainless steel stent? If so what part?

The statement "in order to reduce the initial stretching and to allow the material to become constricted from heat or cold temperature," is understood to be an assertion of a motivation for the combination, but it is not understood what "initial stretching" is being referred to. Andrews et al doesn't describe an initial stretching of the Fig. 10 stent. Likewise what does "becoming constricted from heat or cold temperature" have anything to do with the Andrews et al stent? In Fig. 10 of Andrews et al, the stent is being implanted in the body where it is presumably at human body temperature. Still further, in what way will the addition of annealed polypropylene fibers increase the final molecular orientation of a stainless steel stent?

All of these problems with the rejection as articulated by the Examiner were raised in response to the first Action in this application. None of them have been addressed in the Final Action. The Examiner simply repeated the initial rejection verbatim.

Furthermore, the applicant does not understand the phrase "then annealed in an oven," and does not see how it relates to performing an annealing step after radial expansion of a stent or tube.

In any case, as we have noted with respect to the Stinson patent, use of annealed fibers to form a stent is irrelevant to the annealing steps recited in the various process claims.

The Examiner has not identified a reasonable motivation to combine the Andrews et al and Lennard et al patents and has not shown how any combination of teachings in these documents could produce the invention of any of claims 1, 13, 15, 17 and 21 Reversal of the rejection under 35 USC §103 is therefore respectfully requested.

b. Claims 1, 15, 17, and 21 - Annealing Sequence

Claims 15 and 17 pertain to processes for forming tubular articles, as to which Andrews et al's balloon forming process might be of interest. However, the steps of that balloon forming process are very different. In Andrews et al a composite tube is formed [col. 8, ln. 6-26, Fig. 1], stretched to a ***reduced diameter*** [col. 8, ln 27-33; Fig. 3], the ends are then heated [col. 8, ln. 34-46], after which the material is cooled and stretching is released to allow the tube to return to its original diameter, except for the ends that had been heated [col. 8, ln 47-56, Fig 5].

In claims 15 and 17, and in the stent forming process claims 1 and 21 as well, the annealing steps are all performed in a sequence and occur after a ***radial expansion*** of a formed stent or a formed tube. To the extent that end heating step of Andrews et al is considered an annealing step, it follows a ***radial reduction*** step. The Andrews sequence for balloon formation therefore cannot be considered to render obvious the processes of claims 15 or 17, much less of claims 1 and 21.

c. Claims 1 and 21 - Polymer Stent Forming Process

Claims 1 and 21 pertain specifically to processes for forming polymer stents. Since neither Andrews et al nor Lennard et al describe stent forming process, much less a polymer stent formation process, these claims cannot be rendered obvious by the combination, even if such a combination was properly motivated.

d. Claim 13 - Polymer Stent

Because the only mention of a stent in either patent is a metal stent, claim 13, which is directed to a polymer stent, is also not *prima facie* obvious. Moreover, claim 13 also recites that material has hoopwise molecular orientation. Since neither Andrews et al nor Lennard et al show a polymer stent, hoopwise orientation of such a stent cannot be obvious therefrom.

e. Claim 15 - Repetition of the Radial Expansion and Annealing Steps in Sequence

As previously described, Claim15 requires repetition of steps (b) and (c) at least one time in sequence. The Examiner has not shown where this feature can be found in the Andrews et al or Lennard et al.

f. Claim 17 - Biodegradable Material

Claim 17 recites a process for forming a tubular article in which the polymer material is biodegradable. Andrews pertains to formation of balloons, the disclosed materials of which (PET and polyurethane) are not considered biodegradable, and illustrates use with a stainless steel stent, also not biodegradable. Lennard et al describes a process for forming polypropylene sutures. Polypropylene sutures resist breakdown, have minimal reaction with tissue, and maintain strength in vivo over extended periods [Lennard et al, col, 1, ln. 16-24], all identified by Lennard as advantages of the material. The skilled person would not consider the Lennard et al to teach or suggest use of a biodegradable polymer material for sutures, much less in a process for forming a tubular article.

f. Claim 21- Stent Pattern Formed From a Tube That Has First Been Subjected To Sequential Radially Expansion and Annealing Steps

As previously described, in claim 21 a polymer tube is formed, radially expanded, the radially expanded tube is annealed, and subsequently the stent is formed from the annealed tube. That is, the stent pattern is provided ***after*** the tube has been both b) radially expanded and c) annealed. Neither Andrews et al nor Lennard et al show a process for forming polymer stent, much one in which the stent is formed from a tube after it had been radially expanded and then annealed.

3. Conclusion

The Examiner has made numerous mistakes in characterizing the disclosures of the Stinson, Andrews et al and Lennard et al patents. Claims 1-23 are not anticipated by the Stinson patent. The Examiner has not shown a motivation to combine the Andrews et al patent and the Lennard et al patents and when combined, the teachings of those patents still fail to teach or suggest the subject matter of any of claims 1-23. Claims 1-23 therefore are not obvious from

Andrews et al taken with Lennard et al. The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: February 14, 2005

By: _____
Walter J. Steinkraus
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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(viii) Claims Appendix

(viii) Claims appendix. An appendix containing a copy of the claims involved in the appeal.

1. (Previously Presented) A process for forming a stent of a polymer material, the process comprising the steps of:

a) forming a generally tubular stent of said polymer material;

b) radially expanding the stent to produce an expanded diameter stent; and then,

c) annealing the expanded diameter stent to shrink its diameter to a reduced diameter.

2. (Original) A process as in claim 1 further comprising at least one time repeating steps b) and c) in sequence.

3. (Original) A process as in claim 1 wherein in step a) the stent is formed by molding the polymer material.

4. (Original) A process as in claim 3 wherein the polymer material is thermoplastic.

5. (Original) A process as in claim 4 wherein the polymer material is biodegradable.

6. (Original) A process as in claim 1 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

7. (Original) A process as in claim 6 wherein the polymer material is a poly(alpha-hydroxy acid) selected from the group consisting of homopolymers and copolymers of polylactide (PLA), poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, poly(hydroxybutyrate), polygluconate, and mixtures thereof.

8. (Original) A process as in claim 1 wherein the step b) is performed at a temperature below the glass transition temperature of the polymer material.

9. (Original) A process as in claim 8 wherein the step b) is performed at room temperature.

10. (Original) A process as in claim 1 wherein the step c) is performed at a temperature above the glass transition temperature of the polymer material.

11. (Original) A process as in claim 10 wherein the step c) is performed at a temperature within the range of about 90□C to about 150□C.

12. (Original) A thermoplastic polymer stent having a molecular orientation as obtained by a process as in claim 1.

13. (Original) A thermoplastic polymer stent having a hoopwise molecular orientation.

14. (Original) A stent as in claim 13 wherein the thermoplastic polymer is biodegradeable.

15. (Original) A process for forming a tubular article of a polymeric material, the process comprising the steps of:

a) forming a generally tubular article of said polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter.

and wherein at least one time steps b) and c) are repeated in sequence.

16. (Original) A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 15.

17. (Original) A process for forming a tubular article of a polymeric material, the process comprising the steps of:

a) forming a generally tubular article of said polymeric material;

b) radially expanding the article to produce an expanded diameter article; and then,

c) annealing the expanded diameter article to shrink its diameter to a reduced diameter and wherein the polymer material is a biodegradable polymer.

18. (Original) A process as in claim 17 wherein at least one time steps b) and c) are repeated in sequence.

19. (Original) A process as in claim 17 wherein the polymer material is selected from the group consisting of poly(alpha-hydroxy acid), polylactic acid-polyethylene oxide copolymers; modified cellulose; collagen or other connective proteins; adhesive proteins; hyaluronic acid; polyanhydrides; polyphosphoesters; poly(amino acids); copolymers thereof; and mixtures of any of said materials.

20. (Original) A medical device adapted for body lumen navigation and/or treatment produced by the process of claim 17.

21. (Original) A process for forming a stent of a polymeric material, the process comprising the steps of:

a) forming a tube of said polymeric material;

b) radially expanding the tube to produce an expanded diameter tube;

c) annealing the expanded diameter tube to shrink its diameter to a reduced diameter; and subsequently

d) forming a stent from the annealed tube.

22. (Original) A process as in claim 21 wherein the steps b) and c) are repeated at least once before step d) is performed.

23. (Original) A process as in claim 21 wherein in step d) the stent is formed by machining or etching the reduced diameter tube obtained from step c).

(ix) Evidence appendix. An appendix containing copies of any evidence submitted pursuant to §§1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See §41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.

Not applicable

(x) Related proceedings appendix. An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

Not applicable

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See §1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and §41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of §1.136 of this title for patent applications and §1.550(c) of this title for ex parte reexamination proceedings.